REMARKS/ARGUMENTS

This paper is filed in response to the Office Action mailed on July 29, 2003.

Claims 1, 2, 4, 10 and 13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys (U. S. Patent No. 4,657,024). Claim 14 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys and Hopkins. Claims 5, 6, 11 and 12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys as applied to claims 1, 2, 4, 10 and 13, and further in view of Hopkins. The reference to Coneys was newly applied in this Office Action.

The present application is directed to an introducer sheath that comprises a shaft body having a short distal tip section bonded thereto. As claimed in claim 1, both the shaft and the distal tip section of the introducer sheath are made of fluorinated ethylene propylene (FEP), and the sections are joined by a thermal bond. The distal tip contains between about 20% and 75% by weight of a specified radiopaque material, and is considerably more radiopaque than the shaft.

For optimal use, an introducer sheath should have certain basic capabilities. For example, an introducer sheath should have sufficient radial rigidity to enable the sheath to remain open following removal of a medical device that had been introduced therethrough. A sheath should also have sufficient flexibility to permit manipulation of the sheath through a body passageway without kinking under conditions of normal use. A sheath should also be formed of a material that has a low coefficient of friction. In many occasions, it is also desirable to form a sheath that includes discrete body sections, such as an elongated shaft body and a short distal tip section, that are bonded together to form the sheath. The body sections can have, for example, different durometers to assist in manipulating the sheath through tortuous body passages, and/or different radiopacity to better enable the physician to monitor the position of a particular body section.

The present inventors have determined that forming an introducer sheath from discrete sections, each formed of fluorinated ethylene propylene, provides a very versatile sheath that avoids many of the problems that presently exist in the art with known sheaths. The FEP sheath of the present invention has sufficient radial rigidity to enable the sheath to

remain open following removal of a medical device introduced therethrough. At the same time, the sheath has sufficient flexibility to permit manipulation through a body passageway without kinking under conditions of normal use. The sheath has a low coefficient of friction, and is formed from a composition (FEP) that physicians are very comfortable and familiar with. The discrete body sections of the sheath also have a distinct difference in radiopacity, and, notwithstanding this difference in radiopacity, are capable of being bonded together in a manner such that the possibility of disengagement under conditions of normal use is minimized.

It is known in the art to provide an introducer sheath with a discrete distal tip portion that is highly loaded with radiopaque materials such as tungsten or barium. The presence of a highly loaded radiopaque tip is advantageous, because it allows the physician to accurately determine the position of the distal tip upon fluoroscopy. In addition, the radiopacity of the tip section allows it to be more easily detected in the event of disengagement from the sheath, so that it can be located and removed from the body. Radiopaque distal tip sections are generally made of copolymers that are amendable to high loadings of the radiopaque materials. Copolymers, however, have a higher coefficient of friction than is desirable in an introducer sheath. Other materials have been used that have a lower coefficient of friction, however such materials do not maintain good flexibility and kink resistance when highly loaded with radiopaque material. In some instances, in order to take advantage of the different properties required of each section, the shaft and distal tip are formed from different polymers that are joined together, by measures such as cold bonding or adhesion. When dissimilar sections are joined together in this manner, the possibility of disengagement of the sections is increased.

Since both the shaft and the distal tip sections of the introducer sheath of the present invention are formed from fluorinated ethylene propylene (FEP), a very favorable bond can be formed therebetween. This is especially true when a thermal bond is created between the two sections. The short bonding zone between the distal tip and the shaft body is an area of very high stress and generally receives the most bending forces. Relatively large differences in material properties across such a short bond zone can concentrate the stresses in the bond zone, and make the bond susceptible to failure. Since the sheath is normally inserted into an artery, the separation of the short tip segment from the remainder of the sheath would result

in a dangerous embolus free floating in the arterial system. The embolus would eventually lodge somewhere and occlude blood flow to tissue. When the FEP sections are thermally bonded a good molecular mix of molten materials results. As the shaft and tip move together, a shearing of the molten material occurs at the interface. This shearing action forces the highly loaded tip material at the interface to blend or mix with the shaft material, resulting in a true molecular mixing or weld between the two materials. This contrasts with an interface between dissimilar materials wherein the molecular mixing doesn't result in a true blend that maintains the properties of each of the sections. It also contrasts with the formation of a mere "cold" bond or adhesive connection between the distal tip and the shaft. Although such connections may initially appear to provide a strong weld or bond, they are in fact much weaker than desired. In the sheath of the present invention, the highly radiopaque tip essentially becomes an integral part of the sheath body, yet maintains its radiopacity to enable it to be viewed under fluoroscopy.

In the Office Action, the Examiner acknowledged that the Parker reference does not teach the use of FEP as either a shaft or distal tip material. Applicants have discussed the Parker reference in previous responses.

The secondary Coneys reference was cited for teaching the use of radiopaque-loaded FEP as the polymeric material in a medical tube. The Coneys patent teaches a medical-surgical tube formed from an extruded tube of flexible material, such as FEP. Layers of pure, virgin FEP define the entire interior and exterior surfaces of the tube to provide smooth surfaces having a low coefficient of friction. A radiopaque layer is fully embedded within the tube, and is completely surrounded by the pure FEP layers. According to the background material recited in Coneys, mixing radiopaque material with the polymeric material in prior art constructions (that did not include embedded layers) resulted in a catheter that was frequently reactive with body tissues and/or had a rough or coarse exterior surface. When exposed on the exterior of the catheter, the radiopaque material resulted in a relatively high coefficient of friction. This high friction surface caused irritation to the patient, or impaired the insertion of a catheter into a tissue. When exposed to the interior of the tube, the radiopaque material provided a rough surface that frequently caused "bruising" of the blood, and occasionally, clotting. If the radiopacity was not satisfactory, or if detection was required deep within the body, the addition of the radiopaque material in prior art devices was said to

be unacceptable because of its roughness and/or due to its being too reactive. Col. 1, lines 50-68.

Coneys' solution to this recited problem was to prepare a separate, fully embedded, radiopaque layer comprising high amounts (70-80%) of FEP. When the radiopaque layer is embedded in the tube as described in the patent, the radiopaque material comprises between 12-25% of the total weight of the material making up the tube. Thus, the Coneys solution to the problem of high friction was to simply remove the radiopaque particles from the surface, and include them in a separate layer fully embedded in the device. As a result, Coneys does not include a discrete radiopaque section as in the present invention. Furthermore, Coneys does not include radiopaque particles at or near the inner surface, outer surface, or distal end of the device. Rather, the radiopaque particles are fully embedded as a separate layer within the pure FEP.

Contrary to the teachings of Coneys, the sheath of the present invention achieves radiopacity in a very different manner. A low friction radiopaque tip is bonded to the shaft body. The radiopaque tip does not comprise a radiopaque layer embedded within the sheath. Rather, the radiopaque particles are fully dispersed throughout the tip. Since the radiopaque material can be loaded at high levels in the distal tip section, the physician can clearly detect the distal end of the sheath. Such an observation would be inferior with a fully embedded radiopaque layer, where pure plastic fully surrounds the radiopaque layer. Since the distal tip and the shaft body in the inventive sheath are both made of FEP, a very reliable bond can be formed therebetween. This arrangement is much simpler, less costly, and radiographically superior to that taught in Coneys.

The Parker patent does not teach the use of the low coefficient of friction material utilized herein. Whereas Coneys teaches the use of FEP in a medical-surgical device, Coneys teaches away from the present invention by teaching that when high loadings of radiopaque particles are desired in a sheath, the particles must be fully embedded in pure FEP in order to maintain a satisfactory coefficient of friction. This arrangement sacrifices the ability to directly observe the distal portion of the sheath under fluoroscopy. It also adds considerable complexity and cost to the manufacturing process. In addition, it is well known that a desirable feature of an introducer sheath is that is maintain as narrow a profile as possible. The use of an "embedded and surrounded" layer such as taught in Coneys is

counterproductive to this aim, and teaches away from the present invention. Applicants respectfully submit that a skilled artisan searching for a solution to the problem of forming an introducer sheath having a highly radiopaque distal tip bonded to a shaft in a manner such that the resulting sheath has a flexibility similar to that of the shaft, would not find the solution to this problem in the cited combination of references.

Thus, for the reasons provided above, Applicants submit that claim 1 and dependent claims 2, 4, 10 and 13 are allowable over Parker in view of Coneys.

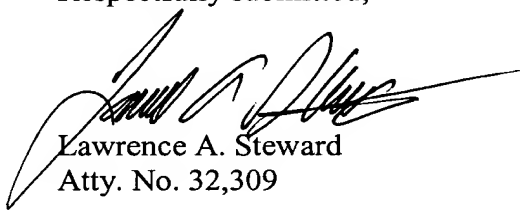
Claim 14 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Parker (270) in view of Coneys and Hopkins, and claims 5, 6, 11 and 12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys as applied to claims 1, 2, 4, 10, 13 and 16, and further in view of Hopkins. Parker and Coneys have been discussed. The Hopkins reference was cited for teaching the use of radiopaque materials such as tungsten in a catheter, and for teaching that particles can be as small as 0.9 microns, which, according to the Examiner, suggests that they can be any size larger than 0.9. The Hopkins patent is directed to a compliant marker band that is heat shrunk over a catheter or sheath, thus eliminating the need for heat or adhesive bonding. Col. 2, lines 34-36; Col. 3, lines 15-17. The marker band surrounds the external surface of the catheter or sheath and includes a radiopaque material such as tungsten.

By using a marker band, Hopkins teaches away from the present invention by employing technology that the present inventors desire to avoid. The use of a marker band that is heat shrunk or otherwise positioned over a sheath increases the thickness of the sheath wall, and thereby imparts a certain amount of rigidity to the sheath. In addition, the use of a radiopaque marker band forces the operator to estimate the precise location of the distal tip of the device. In the present invention, the radiopaque marker is the distal tip, thereby eliminating this guesswork. Applicants do not dispute that highly radiopaque marker bands are known in the art. However, the Hopkins reference does not teach or suggest the use of FEP in an introducer sheath for the purposes described, nor does it teach or suggest that a distal tip can function as a radiopaque marker. In addition to the foregoing, one skilled in the art would not likely make the cited combination, since Hopkins also teaches away from a purpose of the present invention, namely the use of a highly loaded distal tip, instead of a

marker band. Thus, Applicants respectfully submit that claims 5, 6, 11, 12 and 14 are allowable in view of the cited combination.

Based upon the remarks provided hereinabove, Applicants respectfully submit that all claims 1, 2, 4-6 and 10-14 are allowable over the combination of references discussed hereinabove. Accordingly, Applicants respectfully request that the Examiner reconsider the previous rejections in view of these claims. If the Examiner believes that prosecution of this application may be expedited by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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